## REMARKS

Claims 1-20 are pending in this application. The specification, drawing and claims have been objected to, and certain claims have been rejected in view of the prior art. These objections and reasons for rejections are respectfully traversed. Claims 5-8, 15-18 and 20 have been deemed to recite allowable subject matter and applicants gratefully acknowledge this indication of patentability.

**Objection and Informalities**

The references cited in the background section of the specification explain the condition treated by the present invention and the medical and pharmacological treatments of congestive heart failure. These references are not intended to be submitted as relevant prior art. Accordingly, no Information Disclosure Statement is filed herewith.

The drawings have been objected to. Applicants submit that in FIG. 2 is an idealized or symbolic representation of the location of the pump and for this reason, when read in conjunction with the specification, is sufficient to explain the invention. Applicants also respectfully submit that FIGS. 3-5 are explained in the specification, at page 17 of the specification as filed, paragraph 0039 of the substitute specification, bridging pages 14-15. For these reasons, it is respectfully submitted that the objections to the drawings should be withdrawn.

With regard to the substitute specification, a marked up copy was not submitted since the specification is identical to the specification as filed. The document was re-formatted to include paragraph numbering and fonts and margins were changed. Formal

drawings were also supplied. No new matter was inserted. Therefore, entry of the substitute specification is respectfully requested.

An amended abstract in conformance with the rules is submitted herewith. Approval and entry is respectfully requested.

The informalities in the specification have been corrected. Approval of same is respectfully requested.

Claims 19-20 have been objected to, and the informality noted in the Office Action has been corrected. Withdrawal of this objection is respectfully requested.

Claims 1-20 have been rejected under 35 USC Section 112 second paragraph due to the lack of antecedent basis for certain limitations. This reason for rejection is respectfully traversed. By the amendments enclosed herewith, antecedent basis has been supplied for all limitations. Withdrawal of this rejection is respectfully requested

**Prior Art Rejections**

Claims 1-2 and 11-12 have been rejected under 35 USC Section 102 as being anticipated by U.S. patent 4,705,507--Boyles. This reason for rejection is respectfully traversed. Claims 1 and 11 have been amended to recite the chronic and implantable nature of preferred embodiments of the present invention. In terms of claim 1, positive structure is now recited to distinguish the shunt of the present invention from the arterial catheter described in Boyles. With regard to claim 11, the method steps also reflect these same differences between Boles and the present invention.

In order for a reference to anticipate a claim, each and every limitation of the claim must be disclosed in the reference. Accordingly, in view of these remarks and the amendments to claims 1 and 11, withdrawal of this rejection is respectfully requested

Claims 9 and 19 have been rejected under 35 USC Section 103 as being obvious in view of Boyles. Claims 3-4, 10 and 13-14 have been rejected under 35 USC Section 103 as being obvious in view of Boyles in combination with U.S. Patnet 5,584,803—Stevens. These reasons for rejection are respectfully traversed.

By the amendments enclosed herewith, all the rejected claims have been amended to depend from a claim that has been indicated as being allowable. Withdrawal of these reasons for rejection is respectfully requested.

**Allowable Subject Matter**

The Office Action indicates that claims 5-8, 15-18 and 20 would be allowable if rewritten in proper independent format. Applicants have rewritten claim 5 as an independent claim substantially incorporating the limitations of claims 1 and 2. Claim 15 has been similarly re-written substantially incorporating the limitations of claims 11 and 12.

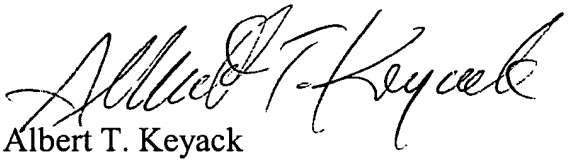
Review and allowance of claims 5 and 15 is respectfully requested.

**Conclusion**

For all these reasons, the present application is now in a condition to be allowed. All the pending claims patentably define the present invention over the prior art.

Accordingly, reconsideration of this application is respectfully requested and a Notice of Allowance is earnestly solicited.

Respectfully submitted,



Albert T. Keyack
Reg. No.: 32,906
Attorney for Applicants

ATK:gj
(215) 563-1810

electrical battery or an externally coupled energy source. A third type of preferred embodiment of the invention employs ~~an~~ a device such as a pump to actively move blood, with the intent of preventing further deterioration of the patient's heart failure or allowing for some reversal of the heart failure. For example in patients presenting with diastolic heart failure (DHF) the present invention prevents this occurrence by reducing diastolic pressures in the left atrium below the excessive levels that would otherwise have caused pulmonary edema.

**Please replace paragraph 0017 on page 8 with the following:**

**FIG. 2** is a side elevation view, in cross-section as ~~shon~~ shown by lines 2-2 in FIG.1, illustrating the placement of the shunt shown in FIG. 1 in a septum, and showing diagrammatically the use of a pump to augment flow in certain embodiments; and

**Please replace paragraph 0019 on page 8 with the following:**

Referring now to FIG. 1, there is shown a perspective view of a first embodiment of a shunt 100 made in accordance with the present invention. The shunt 100 is comprised of a fixation element 110, which is shown as a planar circular element. It will be understood, however, that the fixation element 110 can be circular, polygonal, spiral or many other shapes. Moreover, the fixation element can lie in a single plane or be curved in multiple planes, such as in a helical configuration. It can be constructed of a variety of materials that offer the elastic range and spring-like characteristics that will enable passage through a catheter lumen, or through the lumen of another implantation assistance device, in a relatively straightened configuration and then recovery of its full fixation configuration shape. In certain embodiments, the fixation element can be made of reduced size and then expanded through the use of shape-memory alloys (SMA's), such as nickel-titanium (NiTi, also known as nitinol), that change shape in response to temperature changes and which are fabricated such that the temperature change from

below body temperature to body temperature causes the shape conversion necessary for implantation. If SMA materials are not used, suitable materials include super-elastic metals, such as NiTi, or stainless steel, such as the alloy Elgiloy®~~Elgiloy~~, commonly used for medical implants. Additionally, polymeric materials can be used to form the fixation element or as a coating over a metallic core. The fixation element may be coated and/or textured as so as to increase its biocompatibility or to increase the degree to which it quickly becomes endothelial zed, which may be desired in some implantation conditions.

**Please replace paragraph 0024 on page 10 with the following:**

In accordance with the present invention, the device may or may not include the valve element 130, since in certain patients or to treat certain conditions a valve would add complexity while not providing necessary functionality. Similarly, depending upon the circumstances of use, the valve element 130 may be either passive (actuated by the force of blood) or active (actuated by some other portion of the device). In active valve embodiments, the valve element 130 may include electric or electromagnetic elements that can be selectively actuated to open and close the valve element 130 or, if the valve element is designed for gradual opening and closing, move the valve element 130 between a first position~~positions~~ and a second position. In some embodiments, the valve will be chosen and designed so that it responds only upon certain conditions occurring within the heart, such as the following: absolute left atrial pressure, differential atrial pressure, other intra-cardiac pressures, other cardiovascular pressures, or other physiological conditions that might correlate to an exacerbated state of diastolic heart failure, such as blood oxygen saturation or pH. In such embodiments, response to any given pressure or differential pressure will imply that a portion of the implanted device is in fluid communication with the relevant pressure source or sources. These embodiments will provide robust and reliable functionality by being mechanical and operating with signal inputs. All shunts, whether they include a valve or not can be further enhanced by

including a check-valve that will prevent backflow. Those of skill in the art will appreciate that it is typically desirable to prevent flow from the right heart to the left heart, and thus one or more check valves can be appropriately placed. A double-check valve allows blood pressure above a lower limit but below a higher limit to actuate the valve, thus in a preferred embodiment, shunting blood from the left side to the right side only during a period of diastole.

**Please replace paragraph 0032 on page 13 with the following:**

The pressure/flow/volume requirements of the various embodiments of the present invention will be determined using methodologies similar to those used to design a Left Ventricular Assist Device (LVAD) but with certain distinctly different flow requirements, rather than the intent of supporting systemic circulation requirements found in a LVAD. Thus, certain shunts made in accordance with the present invention can use designs and dimensions that would not be appropriate or adequate for an LVAD. Patients with hear heart failure dominated by systolic dysfunction exhibit contraction abnormalities, whereas those in diastolic dysfunction exhibit relaxation abnormalities. In most patients there is a mixed pathophysiology. Normal pulmonary venous pressure (PVP) necessary for the normal LV to adequately fill and pump is less than 12 mmHg. Patients with systolic dysfunction have larger LV volume to maintain SV and may need increased PVP to fill (mixed systolic diastolic dysfunction). Patients with diastolic dysfunction need increased PVP for the LV to fill and adequately pump.

## Marked-Up Version Showing Changes Made in the Claims

**Please Amend claims 1-2, 5, 8, 11-12, 15, and 18-19 as follows:**

1. (Amended) Chronic implant ~~A~~apparatus for decreasing pressure in a first portion of a vessel of ~~the~~ a cardiac structure of a patient comprising a shunt implanted in the cardiac structure communicating with an area outside said first portion, whereby a volume of blood sufficient to reduce pressure in said first portion is released.

2. (Amended) The apparatus of claim 1, wherein the first portion comprises the left ventricle and said pressure is the end diastolic pressure in a patient heart, wherein said shunt is implanted in a septum defining the left ventricle and communicates with the left ventricle, whereby a ~~small~~ volume of blood is released from the left ventricle to reduce the end diastolic pressure.

5. (Amended) ~~The apparatus of claim 2,~~ Apparatus for decreasing pressure in a left ventricle of a patient comprising a shunt communicating with an area outside said first portion, whereby a volume of blood sufficient to reduce end diastolic pressure in a patient, wherein the shunt comprises a semi-passive check-valve comprising a valve activated by an external signal and communicates with the left ventricle, whereby a volume of blood is released from the left ventricle sufficient to reduce the end diastolic pressure.

8. (Amended) The apparatus of claim ~~25~~ 25, further comprising a pump in fluid communication with the shunt and having an input connected to the left ventricle and an output connected to a volume of lower pressure.

11. (Amended) A method of decreasing pressure in a first portion of a vessel of ~~the~~ a cardiac structure of a patient comprising the step of puncturing a vessel wall between the first portion and another portion and implanting a shunt communicating with an area outside said first portion, whereby a volume of blood sufficient to reduce pressure in said first portion is released.

12. (Amended) The method of claim 11, wherein the first portion comprises the left ventricle and said pressure is the end diastolic pressure in a patient heart, wherein said shunt is implanted in a septum defining the left ventricle and communicates with the left ventricle, whereby a small volume of blood is released from the left ventricle to reduce the end diastolic pressure.

15. (Amended) ~~The method of claim 12,~~ A method of decreasing end diastolic pressure in a left ventricle of a cardiac structure of a patient comprising the step of implanting a shunt communicating with the left ventricle and an area outside the left ventricle, whereby a volume of blood sufficient to reduce end diastolic pressure is released, and further comprising the step of actuating a semi-passive check-valve by an external signal.

18. (Amended) The method of claim ~~12~~15, further comprising the step of activating a pump in fluid communication with the shunt and having an input connected to the left ventricle and an output connected to a volume of lower pressure.

19. (Amended) The method of claim ~~12~~15, further comprising the step of implanting said shunt, said implanting step comprising the step of deploying a tubular element having two ends and a tissue affixation element disposed at each of said ends via a catheter.

## Marked-Up Version Showing Changes Made in the Abstract

~~The present invention is thus directed to methods~~ Methods and apparatus for decreasing cardiac pressure in a ~~first portion of a vessel of the cardiac structure of a~~ patient by implanting a shunt communicating with an area outside ~~said~~ a first portion, whereby a volume of blood sufficient to reduce pressure in ~~said~~ a first portion is released ~~are disclosed~~. Preferably, ~~the first portion comprises the left ventricle and the pressure reduced is~~ the end diastolic pressure in the left ventricle is reduced, which is accomplished by having the shunt communicate with the left ventricle so a small volume of blood is released from the left ventricle ~~to reduce the end diastolic pressure~~. Most preferably, the shunt selectively permits flow when a pressure differential between the left ventricle and another chamber of a heart above a threshold pressure, ~~whereby~~ so that shunting is prevented during left ventricular systole, or, alternatively, selectively permits flow when a pressure differential between the left ventricle and another chamber of a heart is between a lower threshold and a higher threshold~~, whereby shunting is again prevented during left ventricular systole~~. In certain embodiments a semi-passive check-valve is controlled and actuated by an external signal~~, either using a signal generated by an intra-corporeal electrical battery or an externally coupled energy source. In certain embodiments, the shunt has a pump with an input connected to the left ventricle, or other portion with excessive pressure, and an output connected to a volume of lower pressure. The preferred method of implanting the shunt to effect the present invention is by deploying a tubular element having two ends and a tissue affixation element disposed at each of said ends via a catheter, preferably, the fixation element is a shape retaining metallic material that returns to its original shape as part of the retention aspect of its function. In preferred embodiments of the apparatus, the tubular element is comprised of a biologically inert non-metallic material~~.